

Request for Continued Examination

The request filed on 3/31/2008 for a Continued Examination (RCE) under 37 CFR 1.114 based on Application No.10751736 is acceptable, and a RCE has been established. An action on the RCE follows.

Claims 1, 2, and 5-7 are pending and the claims, drawn to a method of diagnosing or monitoring colon cancer in a subject comprising detecting levels of GPR49 protein are examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 2, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated Glucksmann et al., (US Patent application publication, No, 2001/0044130, published Nov 2001) as evidenced by Gaitanaris et al., (US Patent Publication No.US20060134109)

Claims are drawn to a method of diagnosing or monitoring colon cancer in a subject, comprising detecting and comparing a level of expression GPR49 polypeptide in a biological sample of a subject; wherein the GPR49 polypeptide is over-expressed in colon cancer tissues as compared to disease-free colon tissues, wherein the biological sample is a colon tissue sample, a blood sample, or a bodily waste sample, wherein the subject has colon cancer, wherein the subject is subject to a therapeutic treatment of said cancer.

Claim is also drawn to a method of diagnosing or monitoring colon cancer in a subject, comprising the steps of: detecting an expression profile of one or more colon cancer genes in a biological sample of a subject; and comparing the expression profile to a control expression profile of said one or more colon cancer genes, wherein each of said one or more colon cancer genes is differentially expressed in colon cancer tissues as compared to disease-free colon tissues, wherein said one or more colon cancer genes is GPR49, which is over-expressed in

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colon cancer.

The specification describes that method is used for diagnosing a colon cancer by detecting the colon cancer protein (CCP) or its variants including allelic variants (para 22 etc.).

G-coupled protein receptors (GPR) are family proteins with significant sequence homologous as evidenced by Gaitanaris et al., (figure 1, or para 466). Glucksmann et al., disclose a method of detecting and comparing the differential expression of a G-protein-coupled receptor (protein 39406) in normal colon (disease free colon tissue) and differentiated colon cancer tissues (para 11, 35 and 38, figure 6 and 9). Glucksmann et al., also disclose that the biological samples include the tissues, cells, and biological fluids isolated from patients or normal individuals are used for detecting the protein levels with an antibody to the protein (para 144-148). Glucksmann et al., further disclose that the differential expression of the G-protein-coupled receptor is determined by comparing the level of the protein expressed by the cells in colon cancer tissue to normal colon tissues and also disclose the expression of the protein by colon cancer tissue is up-regulated (figure 6).

The method of the prior art appears to meet the requirements of the instant claimed method and steps regarding diagnosing colon cancer by the detecting and comparing the G-protein coupled receptor protein because the high homology of the proteins, which would be recognized by an antibody binding to the homologous sequences in both proteins. Regarding the limitations of the sequence of G-protein coupled receptor 49, the Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the product in the claims. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

2. Claims 1, 2, and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Gaitanaris et al., (US Patent Publication No.US20060134109, priority to Sep 9, 2002).

Claims are set forth above.

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Gaitanaris et al., disclose a method of diagnosing a disease condition comprising the method steps of detecting and comparing a levels of expression GPR49 polypeptide in a biological sample of a subject (para 2, para 21-22; page 148, para 0966-0969). Gaitanaris et al., also disclose the differential expression of GPR49 indicates colon disease comprising colon cell carcinoma (table 16, page 101-102, para 685).

For this rejection the preamble of diagnosing colon cancer in a subject does not limit the claims because the only active steps in these claims are detecting and comparing the expression of GPR49 in biological samples comprising colon tissues. The method of Gaitanaris et al., teach the method steps and therefore, teach each and every limitation of the method. In addition, for this rejection, the phrase "wherein the GPR49 is over-expressed in colon cancer tissues" is not considered as an active method step. The wherein clause is interpreted as a mental step.

3. Claims 1, 2, and 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Afar et al., (US Patent Application Publication, No, 2003/0232350, priority to Nov, 29, 2001) as evidenced by sequence search result (provided in the Office action dated 7/28/2005).

The claims are set forth above, wherein the subject to a therapeutic treatment.

It is noted that GPR49 is differentially expressed in the colon cancer than normal cancer tissues. It is considered as a colon cancer gene.

Afar et al., disclose a method of diagnosing cancer including colon cancer by detecting the expression of genes comprising GPR49 protein expression (para 2 and 92) as shown in protein sequence search result for GPR49, SEQ ID NO: 84 (provided in the Office Action dated 7/28/2005). Afar et al., disclose that the differential expressions of the gene(s) is comparison of the colon cancer tissues to the normal colon tissues and disclose cancer genes (comprising GPR49) are those up-regulated in cancer as compared to non-cancer (para 68, 69). Afar et al., also disclose that the biological samples are obtained from subjects having a treatment history or outcome history, which is subjected to therapeutic treatment of the cancer (para 19).

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao, Ph.D./
Examiner, Art Unit 1642

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643